d.) Remarks

The non-elected claims have been cancelled as appropriate in order to reduce the issues. Claims that should be rejoined later have been amended for better clarity. Additionally, Claim 1 has been awarded to better recite the patentable nature of the present invention. No new matter has been added.

The disclosure has been objected to for the formal reasons noted. In response, Applicants have amended the specification to delete the instance of executable code pointed out by the Examiner. If any further instances are noted, they too shall be attended to promptly.

Claims 1-6 and 18 are rejected under 35 U.S.C. §101 because the claimed invention "lacks patentable utility", e.g., is not supported by either a specific and substantial asserted utility or a well-established utility. The Examiner states that "while the name of the protein is EBI, reminiscent of Epstein Barr induced, there is no evidence found in the specification that the current nucleic acid or protein are induced by infection with Epstein Barr virus."

However, as taught in the specification, those of ordinary skill are aware that "family", referring to protein and nucleic acid molecules, means that it has common structural domain and high homology. These features are explicitly met by the present invention. Indeed, there are unique domains found in both molecules. For instance, human cytokine receptor (EBI-3) mRNA is 99.3% identical at to EPI-3-alt from nucleotides 170-860. Accordingly, those of ordinary skill would plainly expect the subject matter of the present invention to be a member of the Epstein Barr virus family. This is all the statute requires, that the skilled artisan would accept as given that the claimed subject matter is, more likely than not, useful.

As noted, the claims are rejected under 35 U.S.C. § 101 as not having a

specific and substantial utility that is credible (USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1098). In this regard, the Examiner necessarily contends the activity of the present invention is not credible, apparently since those of ordinary skill recognize protein activity cannot be predicted from known homologous sequences. According to the Examiner, implicitly at least, the pending claims do not satisfy the utility requirement of 35 USC 101 because, given the state of the art, structure-function analysis is unpredictable. This basis of rejection is, respectfully submitted, without foundation either in law or in fact.

The Examiner's point concerning the unpredictability of protein activity from known homologous sequences is not well-taken by those of ordinary skill. See, e.g., Principles of Protein Structure, Cantor, ed. (1978) 167 wherein it is explicitly taught that

> "[h]omologous proteins result from speciation or differentiation. Comparisons between homologous proteins have yielded general rules for protein structures (citing Schulz, Angew. Chem. Int. Edit., Vol. 16 (1977) 23-33). . . . In this context it is often useful to distinguish between protein speciation and protein differentiation (citing Molecular evolution and Polymorphism, Kimura ed. (1977) National Institute of Genetics, Mishima, Japan). Speciation is the evolution of homologous proteins possessing a common function in different organisms."

This knowledge is summarized in the art as evidencing that establishing homology between the unknown and reference proteins permits the skilled artisan to assume the unknown unexpressed protein and the known reference protein have the same function. Functional Genomics, Science, Vol. 278, No. 601 (1997).[1/]

Additionally, the USPTO recognizes the state of this art in Example 10 of the Utility Training Materials: DNA fragments encoding a Full Open Reading Frame (ORF). In the example the Examiner is directed not to reject the claims merely because the applicant's asserted utility is premised on the "overall level of sequence similarity between SEQ ID NO:3 [the unknown sequence] and the consensus sequence of the known DNA ligases that are presented in the specification." Indeed, Example 10 acknowledges that "homology between the known and unknown protein is sufficient to ascribe the known protein's function to the unknown; thus the claim possesses credible, substantial, and specific utility." Id. at 54.

Again, utility is well-established if, as here, it is readily apparent to one skilled in the art. Id. at 55.

Indeed at the very least, the resemblance of the present invention to specific EBI-3 nucleotide and protein makes clear the present invention can be further utilized as research tools for better characterizing those prior art compounds. Regarding this point, even this asserted utility (e.g., to better characterize EBI-3 materials), such is specific. That is, while "specific utility" excludes generalized research tools like probes, this is not

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1/ This is not an aberrant position; similarly, the American Society of Human Genetics ("ASHG") similarly acknowledges "sequence homology is a useful predictor of gene function." Letter from Ronald Worton, Ph.D., President, ASHG, to the Honorable Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Unites States Patent and Trademark Office at 2 (Mar. 22, 2000) (on file with the USPTO).

so, however, when the gene being probed for is already known. Revised Interim Utility Guidelines Training Materials at 50-53.

Accordingly, respectfully submitted, the rejection under 35 U.S.C. § 101 is without bases in fact and in law, and withdrawal thereof is earnestly solicited.

Claims 1-6 and 18 are also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility. Moreover, the claims have been amended without prejudice, so as to reduce the issues, in order to delete materials such as fragments and the like. Accordingly, this rejection is overcome.

Claims 1, 3-6 and 18 stand rejected under 35 U.S.C. §112, first paragraph, as failing to be supported by an adequate written description. The bases for this rejection are unclear, since these are original claims and so, provide their own written description. Nonetheless, in effort to reduce the issues and expedite prosecution herein, claim 1 has been above amended without prejudice in order to address the Examiner's concerns. Accordingly, this rejection also is believed to be overcome.

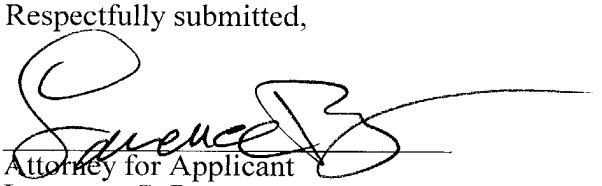
Claims 1, 3-6 and 18 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,744,301 to Birkenbach which is said to show a local region of 99.3% similarity and overlapping regions greater than 30 nucleotides. In response, claim 1 has been amended to delete fragments. Moreover, since the claims require 75% homology of the entire nucleic acid sequence, the local homology is irrelevant. Inasmuch as these features are neither taught nor suggested by Birkenbach, this rejection is mooted and should be withdrawn.

In view of the above amendments and remarks, Applicant submits that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-7, 12, 16, 17 and 24-29 remain presented for continued prosecution.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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